

REMARKS

Claims 23-46 remain in this application. Claims 43-45 have been withdrawn. The specification, and claims 23, 25, 35 and 42 have been amended. Support for the amendments can be found in the specification, and in US 5,043,323 fully incorporated by reference, thus, no new matter has been added.

Objection to the Specification

At page 2, the Office Action objects to the specification, in particular, the Abstract. The Office Action requires the applicants to delete "The invention is directed to" on line 1 of the Abstract. Applicants have amended the Abstract to be even more clear and concise, and to be more narrative in form. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim Objections

At page 3, the Office Action objects to claims 23-34 because of informalities (misspellings). Amended claims 23 and 25 correctly spell "phospholipid" and "phosphatidylserine", respectively. Applicants respectfully request reconsideration and withdrawal of the objection.

Claims Rejection under 35 USC §112, second paragraph

At page 3, the Office Action rejects claims 23-42 and 46 under 35 USC §112, second paragraph, as being indefinite. Applicants traverse this rejection.

The Office Action alleges that in claims 23 and 35 the phrase "method for the enhancement of cognitive function and mental fatigue..." is not clear. Amended claims 23 and 35 are directed to "a method for the enhancement of cognitive function and alleviation of mental fatigue...". Support for amended claims 23 and 35 can be found in the specification, for example, the title.

The Office Action alleges that claim 42 is unclear because it recites an additional compound as opposed to an additional step. Amended claim 42 is directed to a method "further comprising administering grape seed extract complexed with phospholipids as an additionally active compound." Therefore, amended claim 42 recites an additional step.

The Office Action further alleges that in claim 42 it is not clear what applicant means by "complexed grape seed extract". Amended claim 42 clarifies "grape seed extract complexed with phospholipids...".

Each of claims 23-46 satisfies the requirements of 35 USC §112, second paragraph. Thus, applicants respectfully request reconsideration and withdrawal of the rejection.

Claim Rejections under 35 USC §103

At page 4, the Office Action rejects claims 23-42 and 46 under 35 USC §103(a) as obvious over SUMMERS (U.S. 6,733,797), in view of LOEW (Value of Ginkgo biloba in treatment of Alzheimer dementia, Wiener medizinische Wochenschrift (1946), (2002) Vol.

152, No. 15-16, pp. 418-22, Ref:40). Applicants traverse this rejection.

Independent claims 23, 35 and 36 are directed essentially to a method for the enhancement of cognitive function and alleviation mental fatigue comprising administering to a subject *Ginkgo* complexed with phospholipid and/or phosphatidylserine. As described in the specification, Applicants found unexpectedly that a *Ginkgo biloba* extract complexed with phosphatidylserine can be used to enhance cognitive function and alleviate mental fatigue significantly above the levels provided by the non-complexed extract (see, page 3, lines 16-20 of the International PCT application). Thus, the invention relates to a pharmaceutical or dietary composition comprising a *Ginkgo biloba* extract complexed with phosphatidylserine. As described in the specification, the *Ginkgo*-phosphatidylserine complex can be obtained from a reaction of the active ingredients of an extract of *Ginkgo* with a phospholipid, for example, 10 to 50% phosphatidylserine (see page 5, lines 10-14). The specification further details the preparation of a complex between the *Ginkgo biloba* and phosphatidylserine (see page 6, lines 14-21).

The formation of *Ginkgo* phospholipid complexes enables the preparation of new biologically active compositions. In fact, they possess physico-chemical and spectroscopic characteristics which are markedly different from those of the original components and as such they can be incorporated as active

principals into pharmaceutical formulations. *Ginkgo* shows a strong affinity for phospholipids, resulting in the generation of bonds which markedly modify their physico-chemical and spectroscopic characteristics of these new molecules (see page 6, lines 22-29). SUMMERS fails to teach or suggest such *Ginkgo*-phospholipid complexes, and fails to teach or suggest a method of using such complexes for the enhancement of cognitive function and the alleviation of mental fatigue as presently claimed.

As acknowledged in the Office Action, SUMMERS describes a formulation comprising phosphoesters and antioxidants. The combination may have synergistic effect. SUMMERS, however, fails to teach or suggest a *Ginkgo*-phospholipid *complex* such as that described by the applicants, and as featured in the instant claims. Specifically, SUMMERS fails to recognize that a *Ginkgo biloba* extract *complexed* with phosphatidylserine has significant effects above the non-complexed extract.

The specification shows, in the cognitive assessment tests and results, that *Ginkgo biloba* extract complexed with phosphatidylserine has outstanding effectivity compared with other tested species (i.e. non-complexed *Ginkgo* or *Ginkgo* phosphatidylcholine complex), regarding Quality of Memory, Picture Recognition Accuracy, Speed of Memory, Timed Memory Tasks, and other tasks concerning attention (see page 16, line 16 to page 29, line 5, and Figures 1-6).

Further support for the unexpectedly superior results of a *Ginkgo*-phosphatidylserine complex is provided in the attached Rule 132 Declaration of Ezio Bombardelli. The Declaration includes the results of experiments carried out on 15 subjects, each subject treated with capsules respectively containing: *Ginkgo biloba* extract (GBE); phospholipids containing 20% phosphatidylserine (PS); mechanical mixtures containing *Ginkgo biloba* extract and phosphatidylserine (GBE + PS); and *Ginkgo*-phosphatidylserine complexes (Complex). Speed of Memory, Quality of Memory, and Picture Recognition Accuracy were evaluated as disclosed in the specification. The declaration states that results show capsules containing *Ginkgo*-phosphatidylserine complex show a remarkably higher and statistically meaningful activity than that of capsules filled with *Ginkgo biloba* extract, phosphatidylserine, or mixtures of *Ginkgo biloba* extract and phosphatidylserine. The results of Speed of Memory tests are shown in the graph in the attached Declaration.

SUMMERS fails to teach or suggest the use of *Ginkgo*-phosphatidylserine complex to enhance cognitive function and alleviate mental fatigue. LOEW fails to remedy the deficiencies of SUMMERS. Like SUMMERS, LOEW also fails to teach or suggest the use of *Ginkgo*-phosphatidylserine complexes to enhance cognitive function and alleviate mental fatigue.

For at least these reasons, the combination of SUMMERS and LOEW fails to teach or suggest, and would not have rendered obvious the method of claim 23, claim 35, claim 36, and all of claims 24-34, 37-42, and 46 depending thereon. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

Entry of the above amendments is earnestly solicited. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- ☐ - a terminal disclaimer
- ☒ - a 37 CFR 1.132 Declaration
- ☒ - a new or amended Abstract of the Disclosure
- ☐ - a Replacement Sheet for Figure of the drawings
- ☐ - a Substitute Specification and a marked-up copy of the
originally-filed specification
- ☐ - a verified English translation of foreign priority document

ABSTRACT

The use of *Ginkgo* complexed with phosphatidylserine for the manufacture of a medicament or a dietary supplement for the enhancement of cognitive function and alleviation of mental fatigue, i.e. to improve the speed of memory and memory quality, to increase accuracy and attention in activities in normal healthy subjects, to prevent deterioration of the speed and quality of memory in people with decreased cognitive functions, to counteract cognitive fatigue, and also having an influence on the mood, particularly in healthy children, young adults, middle-aged and/or old people. It is further provided the use of the Ginkgo-phosphatidylserine complex for the treatment and prevention of disease related with decreased cognitive function and increased mental fatigue such as Dementia, and Alzheimer's Disease.